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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/065,330	04/23/1998	AMEAE M. WALKER	2500.097US2	7326

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/08/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

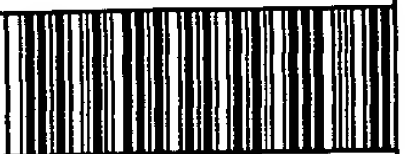
Office Action Summary

Application No.
09/065,330

Applicant(s)
WALKER

Examiner
Christine Saoud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 26, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 October 2002 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed 26 October 2002 have been fully considered but they are not deemed to be persuasive. Claims 1-6 and 9-11 are pending in the instant application.

Claim Rejections - 35 USC § 103

5. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cooke et al. (U.S. Pat. No. 4,725,549) and A. M. Walker (TEM, 5(5): 195-200)

in view of Maciejewski et al. (J. Biol. Chem. 270(17): 27661-27665, 1995, for the reasons of record in paper #13, 16, 25 and 30.

Applicant argues at page 2 of the response that there is no motivation to combine Maciejewski and Walker because one of skill in the art would not believe that Maciejewski et al. teaches that "substitution of serine mimics phosphorylation". This argument is not persuasive because the Maciejewski et al. reference is entitled "Mutation of Serine 90 to Glutamic Acid Mimics Phosphorylation of Bovine Prolactin". Since the journal that this reference was published in is a peer-reviewed journal and very highly thought of in the art, it is clear from its acceptance for publication that the teachings were considered believable to those of skill in the art to which it pertains, absent evidence to the contrary.

Applicant asserts that Maciejewski "makes no claim that their results are generally applicable to other serine residues in prolactin of any species" (see response at page 2). This argument is not persuasive for the following reasons. First, Maciejewski et al. substituted each of the three phosphorylation sites in bovine prolactin, where position 90 was the major site of phosphorylation (by an order of about 10). The substitution of the minor phosphorylation sites did not result in mimicry of the phosphorylation, but substitution of the major phosphorylation site did result in mimicry of phosphorylation. Walker also recognizes that serine 90 in bovine prolactin is the "most favored site", but that the serine at position 177 (with reference to the rat sequence, corresponding to position 179 in the human) is "critical for biological activity of the molecule" and is a major site of phosphorylation (see page 196, column 3 of Walker). Since position 179 is also critical to biological activity, and it is the major site of phosphorylation in the

human molecule, one of ordinary skill in the art would also expect that substitution of this position with glutamic acid would result in mimicry of the phosphorylation as found in the bovine prolactin. This is because these amino acids are analogous and serve similar functions as pointed out by Walker. Maciejewski et al. was not cited for a teaching of substitution of position 179 in human prolactin, only for the teaching that substitution of serine mimics phosphorylation. Walker was cited for the teaching that a serine in prolactin within the region of amino acids 170-180 is highly conserved between species and is a major site of phosphorylation and is critical for biological activity.

Applicant asserts that the Examiner has not provided teaching or suggestion that substitution of the major phosphorylation site in human prolactin would lead to mimicry of phosphorylation. Application is correct, because if such a reference or teaching were available, then the rejection would have been made under 102 for anticipation. The instant rejection is one of obviousness.

6. The Declaration filed on 26 October 2002 under 37 CFR 1.131 has been considered but is ineffective to overcome the Maciejewski et al. reference.

7. Declarations filed under 37 CFR 1.131 are for swearing back of a reference (see MPEP 715). When any claim of an application is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under 37 CFR 1.132 (see MPEP 716). Applicant states at page 3 of the response that the Declaration is under 37 CFR 1.131. The Declaration states that it is under 37 CFR 1.132. The Declaration under 37 CFR 1.132 filed 26 October 2002 is insufficient to

overcome the rejection of claims 1-6 and 9-11 based upon Maciejewski et al. as set forth in the last Office action because: The Declaration is one made by the inventor and merely makes statements of conclusion with no supporting evidence. These statements are not persuasive for the reasons of record and for those provided above. Briefly, the teaches of the Walker reference would instruct one of ordinary skill in the art that the serine at position 90 in bovine prolactin is analogous to position 179 in human prolactin because they are both the major sites of phosphorylation and are critical to biological activity of the prolactin in that species. Therefore, one of ordinary skill in the art would reasonably expect that substitution of glutamic acid for serine, which result in mimicry of phosphorylation in the bovine prolactin, would have the same or similar effect in human prolactin, absent evidence to the contrary.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

8. No claim is allowed.

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal

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communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud